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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,577	04/02/2004	Shilpa S. Thosar	3168/7/US	3792

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/817,577	Applicant(s) THOSAR ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,9,11-17,20-24,26-37,45-47,57-61 and 73-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9,11-17,20-24,26-37,45-47,57-61 and 73-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of RCE, amendment and remarks dated 12-22-2005 is acknowledged.

Claims 6, 8, 10, 18,19 and 25 have been canceled. New claims 77 and 78 have been added. Claims 1-5, 7, 9, 11-17, 20-24, 26-37, 45-47, 57-61 and 73-78 pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 12-22-05 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7, 9, 11-17, 20-24, 26-37, 45-47, 57-61 and 73-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,534,093; claims 1-65 of U.S. Patent No. 6,410,054; claims 1-60 of U.S. Patent No. 6,863,902; claims 1-62 of U.S. Patent No. 6,558,707; claims 1-21 of U.S. Patent No. 6,495,165 and claims 1-10 of U.S. Patent No. 6,592,902. Although the conflicting claims are not identical, they are not patentably distinct from each of the above sets of patented claims. The above patents, except 6,495,165 claim immediate release pharmaceutical compositions containing micronized eplerenone having a particle size between 25 and 400 microns and pharmaceutical excipients that are similar to the instant claims, including the same excipients. The patented claims also recite the percentages pharmaceutical excipients and method of use that are the same as claimed in the instant application. Instant claims do not recite the same amount of eplerenone and instead recites amounts that are encompassed by the patented claims. However, optimizing the amounts of the active agent and the excipients in the eplerenone compositions so as to achieve the desired release rates would have been obvious for one of an ordinary skill in the art at the time of the instant because the above patents recite the same drug, same excipients and also the immediate release compositions as in the instant invention. With respect to 6,495,165, instant claims recite release rates in terms of in vitro dissolution rates, whereas the

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above patent claims in vivo plasma profiles. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare eplerenone composition with a desired release rate as in the instant from the composition of the above patent because patent also claims the same active agent and excipients and optimizing the amounts of a known composition so as to result in a different rate for the treatment of same conditions i.e., block aldosterone receptor, would have been within the scope of a skilled artisan.

Response to Arguments

Applicant's arguments with respect to claims 1-5, 7, 9, 11-17, 20-24, 26-37, 45-47, 57-61 and 73-78 have been fully considered.

In response to amendment and the arguments, the rejection of above claims as being unpatentable over being unpatentable over US 4,559,332 to Grob et al (Grob) in view of Remington has been withdrawn and accordingly the arguments regarding the rejection is moot.

Examiner notes that a double patenting rejection was made in the non-final action dated 10-1-2004. In their response dated 4-1-05, applicants mentioned that the rejection is no longer applicable in view of the amendments. Applicants also stated that upon notification of allowable claims, terminal disclaimer would be filed to advance the prosecution. Upon further consideration, examiner applied the previously made double patenting rejection to the instant claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
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March 14, 2006